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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,259	12/04/2003	David S. Keppel	2878	7800
50855	7590	11/16/2005		
UNITED STATES SURGICAL, A DIVISION OF TYCO HEALTHCARE GROUP LP 150 GLOVER AVENUE NORWALK, CT 06856			EXAMINER WILLIAMS, KENNETH C	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/728,259

Applicant(s)

KEPPEL, DAVID S.

Examiner

Kenneth C. Williams

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 03/08/04, 03/25/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: See Continuation Sheet.

Continuation of Attachment(s) 6). Other: Information Disclosure Statements from 06/10/04 and 09/17/04.

DETAILED ACTION

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The specification identification lists the incorrect U.S. Patent Application filed on December 4, 2003.

Specification

2. The disclosure is objected to because of the following informalities:

The specification is missing a portion of text on the last line of Page 1.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-3, 8 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Oyama et al. (U.S. Patent No. 6663623).

- a. In regards to Claim 1, Oyama et al. discloses an apparatus comprising "an electrosurgical generator" (See Figure 5A; see also column 6, lines 22-34), "a processing unit" (See Figure 5A; see also column 6, lines 24-29) and "a waveform generator" (See Figure 5A, see also column 6, lines 24-29).
- b. In regards to Claim 2, Oyama et al. discloses an apparatus comprising "processing unit further determines a corresponding output crest factor value and output power value for the determined tissue impedance by accessing at least one data structure" (See column 8, lines 29-54).
- c. In regards to Claim 3, Oyama et al. discloses an apparatus comprising "said at least one waveform adjustment signal includes data for setting the output crest factor and output power to the values provided by the at least one data structure" (See column 12, line 49 – column 13, line 20).
- d. In regards to Claim 8, Oyama et al. discloses an apparatus comprising "said processing unit executes the set of programmable instructions automatically, in real time and continuously during electrosurgical activation" (See column 3, line 45 – column 4, line 8).
- e. In regards to Claim 21, Oyama et al. discloses "a power source for generating an output voltage and an output current for an electrosurgical generator system, said electrosurgical system is capable of varying both the output crest factor and output power based on the changing

impedance of tissue during electrosurgery, and said electrosurgical system including a processing unit for receiving at least one signal indicative of the output voltage and the output current, said processing unit executing a set of programmable instructions for determining the tissue impedance using the output voltage and output current and transmitting at least one waveform adjustment signal, said electrosurgical system further including a waveform generator for receiving the at least one waveform adjustment signal for adjusting the output crest factor and output power based on the determined tissue impedance" (See column 8, lines 29-54 and column 12, line 49 – column 13, line 20).

5. Claims 10-13, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Carder (U.S. Patent No. 4961047).

a. In regards to Claim 10, Carder discloses a method comprising "determining tissue impedance using an output voltage and an output current of the electrosurgical generator" (See column 3, lines 20-33) and "adjusting the output crest factor and output power of said electrosurgical generator based on the tissue impedance" (See column 3, line 42 – column 4, line 9). The examiner considers the Carder reference to inherently disclose the applicant's method.

b. In regards to Claim 11, Carder discloses a method (See Claim 10 Rejection). Carder further discloses "said adjusting step comprises the step of determining a corresponding output crest factor value and output

power value for the determined tissue impedance by accessing at least one data structure" (See column 3, line 17- column 4, line 24).

c. In regards to Claim 12, Carder discloses a method (See Claim 11 Rejection). Carder further discloses "said adjusting step comprises the step of setting the output crest factor and output power to the value provided by the at least one data structures" (See column 3, line 17- column 4, line 24).

d. In regards to Claim 13, Carder discloses a method (See Claim 11 Rejection). Carder further discloses, "said at least one data structure includes at least one look-up table" (See column 3, lines 28-33).

e. In regards to Claim 18, Carder discloses a method (See Claim 10 Rejection). Carder further discloses, "the step of manually selecting a value fro the output crest factor and a value for the output power" (See column 3, lines 43-61).

f. In regards to Claim 19, Carder discloses a method (See Claim 10 Rejection). Carder further discloses, "said method is performed automatically, in real time and continuously for the duration of the electrosurgery" (See column 4, lines 25-52).

6. Claims 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Carder (U.S. Patent No. 4961047).

a. In regards to Claim 20, Carder discloses an electrosurgical generator comprising "means for determining tissue impedance using an output voltage and output current of the electrosurgical generator" (See

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column 3, lines 6-33) and "means for adjusting the output crest factor and output power of said electrosurgical generator based on the determined tissue impedance" (See column 3, line 43-24).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Oyama et al. (U.S. Patent No. 6663623) in view of Carder (U.S. Patent No. 4961047).

In regards to Claim 4, Oyama et al. discloses an apparatus (See Claim 2 Rejection). Oyama et al. does not disclose, "said at least one data structure includes at least one look-up table". Attention is directed to the Carder reference, which in an analogous field of endeavor discloses the use of an EPROM containing a look-up table of impedances (See Carder column 3, lines 28-33). It

would have been obvious to one of ordinary skill in the art at the time of the invention to add the teaching of Carder to the apparatus of Oyama et al. to provide a method of comparing tissue impedance during a surgical procedure and a medical standard for tissue impedance.

10. Claims 5-7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oyama et al. (U.S. Patent No. 6663623) in view of Belt et al. (U.S. Patent No. 4191188).

a. In regards to Claim 5, Oyama et al. discloses an apparatus (See Claim 1 Rejection). Oyama et al. does not disclose "said at least one waveform adjustment signal includes data to alter the duty cycle of a waveform generated by the waveform generator in accordance with the following formula: $CF = [(1-D)/D]^{1/2}$ ". Attention is directed to the Belt et al. reference, which in an analogous field of endeavor discloses the teaching of using the duty cycle to control the crest factor (See Belt et al. column 5, lines 29-35). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Oyama et al. with the teaching of Belt et al. to continuously adjust the crest factor.

b. In regards to Claim 6, Oyama et al. discloses an apparatus (See Claim 1 Rejection). Oyama et al. does not disclose "said at least one waveform adjustment signal includes data to alter at least one of the positive peak and the RMS value of a waveform generated by the waveform generator in accordance with the following formula:

$CF = V_{PEAK}/V_{RMS}$ ". Attention is directed to the Belt et al. reference, which in

an analogous field of endeavor discloses the teaching of using the relationship V_{PEAK}/V_{RMS} to alter the crest factor (See Belt et al. column 5, line 45 – column 6, line 14). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Oyama et al. with the teaching of Belt et al. to continuously adjust the crest factor.

c. In regards to Claim 7, Oyama et al. discloses an apparatus (See Claim 1 Rejection). Oyama et al. does not disclose “said at least one waveform adjustment signal includes data to alter at least one of the duty cycle, the positive peak value, and the RMS value of a waveform generated by the waveform generator”. Attention is directed to the Belt et al. reference, which in an analogous field of endeavor discloses an electrosurgical generator that changes the duty cycle to vary the crest factor (See Belt et al. column 5, lines 29-36). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Oyama et al. with the teaching of Belt et al. to utilize the duty cycle to vary the crest factor.

d. In regards to Claim 9, Oyama et al. discloses an apparatus (See Claim 1 Rejection). Oyama et al. does not disclose “at least one control for manually selecting a value for the output crest factor”. Attention is directed to the Belt et al. reference, which in an analogous field of endeavor discloses a panel adjustment element to change the duty cycle that can vary the crest cycle (See Belt et al. column 5, lines 29-36). The examiner

notes that “manually selecting” is not explicitly expressed by the reference, the reference contains the essential structure.

11. Claims 10-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carder (U.S. Patent No. 4961047) in view of Belt et al. (U.S. Patent No. 4191188).

a. In regards to Claim 10, Carder discloses a method comprising “determining tissue impedance using an output voltage and an output current of the electrosurgical generator” (See column 3, lines 20-33). Carder does not disclose, “adjusting the output crest factor and output power of said electrosurgical generator based on the tissue impedance”.

Attention is directed to Belt et al. (U.S. Patent No. 4191188) which in an analogous field of endeavor discloses the teaching of adjusting the crest factor (See Belt et al. column 5, lines 29-36 and column 5, line 46 – column 6, line 39). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Carder with the teaching of Belt et al. to minimize the potential to burn tissue during an electrosurgical procedure.

b. In regards to Claim 11, Carder in view of Belt et al. discloses a method (See Claim 10 Rejection). Carder does not disclose, “said adjusting step comprises the step of determining a corresponding output crest factor value and output power value for the determined tissue impedance by accessing at least one data structure”. Attention is directed to the Belt et al. reference, which in an analogous field of endeavor

discloses the teaching of determining the crest factor (See Belt et al. column 5, lines 46-54). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Carder with the teaching of Belt et al. to minimize the potential to burn tissue during an electrosurgical procedure.

c. In regards to Claim 12, Carder in view of Belt et al. discloses a method (See Claim 11 Rejection). Carder does not disclose "said adjusting step comprises the step of setting the output crest factor and output power to the value provided by the at least one data structures". Attention is directed to the Belt et al. reference, which in an analogous field of endeavor discloses the teaching of setting the output crest factor (See Belt et al. column 5, lines 29-36). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Carder with the teaching of Belt et al. to minimize the potential to burn tissue during an electrosurgical procedure.

d. In regards to Claim 13, Carder in view of Belt et al. discloses a method (See Claim 11 Rejection). Carder further discloses, "said at least one data structure includes at least one look-up table" (See column 3, lines 28-33).

a. In regards to Claim 14, Carder in view of Belt et al. discloses a method (See Claim 10 Rejection). Carder does not disclose "said adjusting step comprises the step of sending a signal to a waveform generator of said electrosurgical generator to alter the duty cycle of a

waveform generated by the waveform generator in accordance with the following formula: $CF = [(1-D)/D]^{1/2}$. Attention is directed to the Belt et al. reference, which in an analogous field of endeavor discloses the teaching of using the duty cycle to control the crest factor (See Belt et al. column 5, lines 29-35). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Carder with the teaching of Belt et al. to minimize the potential to burn tissue during an electrosurgical procedure.

b. In regards to Claim 15, Carder discloses a method (See Claim 10 Rejection). Carder does not disclose "said at least one waveform adjustment signal includes data to alter at least one of the positive peak and the RMS value of a waveform generated by the waveform generator in accordance with the following formula: $CF = V_{PEAK}/V_{RMS}$ ". Attention is directed to the Belt et al. reference, which in an analogous field of endeavor discloses the teaching of using the relationship V_{PEAK}/V_{RMS} to alter the crest factor (See Belt et al. column 5, line 45 – column 6, line 14). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Carder with the teaching of Belt et al. to minimize the potential to burn tissue during an electrosurgical procedure.

c. In regards to Claim 16, Carder discloses a method (See Claim 10 Rejection). Carder does not disclose "said adjusting step comprises the step of said at least one waveform adjustment signal includes data to alter

at least one of the duty cycle, the positive peak value, and the RMS value of a waveform generated by the waveform generator". Attention is directed to the Belt et al. reference, which in an analogous field of endeavor discloses an electrosurgical generator that changes the duty cycle to vary the crest factor (See Belt et al. column 5, lines 29-36). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Carder with the teaching of Belt et al. to minimize the potential to burn tissue during an electrosurgical procedure.

d. In regards to Claim 17, Carder discloses a method (See Claim 10 Rejection). Carder does not disclose "the step of selectively adjusting the output crest factor by adjusting at least one particular parameter of a generated waveform to provide a particular surgical result". Attention is directed to the Belt et al. reference, which in an analogous field of endeavor discloses a method of changing the duty cycle to adjust the crest factor (See Belt et al. column 5, lines 29-36 and column 5, line 45 – column 6, line 23). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Carder with the teaching of Belt et al. to minimize the potential to burn tissue during an electrosurgical procedure.

e. In regards to Claim 18, Carder in view of Belt et al. discloses a method (See Claim 10 Rejection). Carder further discloses, "the step of manually selecting a value for the output crest factor and a value for the output power" (See column 3, lines 43-61).

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f. In regards to Claim 19, Carder in view of Belt et al. discloses a method (See Claim 10 Rejection). Carder further discloses, "said method is performed automatically, in real time and continuously for the duration of the electrosurgery" (See column 4, lines 25-52).

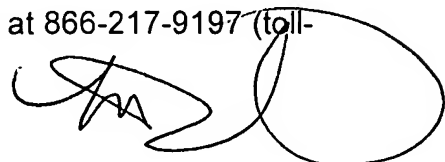
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth C. Williams whose telephone number is (571) 272-8161. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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